



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/626,096	07/26/2000	Robert M Umek	A-68271-2/RFT/RMS/RMK	8157

7590 12/15/2004

Flehr Hohbach Test Albritton & Herbert LLP
Four Embarcadero Center
Suite 3400
San Francisco, CA 94111-4187

EXAMINER

CALAMITA, HEATHER

ART UNIT	PAPER NUMBER
----------	--------------

1637

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/626,096

Applicant(s)

UMEK ET AL.

Examiner

Heather G. Calamita, Ph.D.

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/1/02; 10/18/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1637

DETAILED ACTION

Response to Amendment

1. Cancellation of claims 43-56 is acknowledged. The amendment to the specification concerning the priority data has been entered. The amendment of claim 57 and addition of new claims 58 and 59 are acknowledged.

2. The objections to claim 49-51 are moot due to cancellation of the claims. The obvious-type double patenting rejections of claims 49-51 are moot due to cancellation of the claims. The 102 (b) rejections of claims 43-47 and 52-55 over Bamdad et al. are moot due to cancellation of the claims. The 102 (e) rejections of claims 43-48, 50 and 53-56 over Blackburn et al. are moot due to cancellation of the claims. The 103 (a) rejection of claims 48-50 and 56 are moot due to cancellation of the claims. However, the 102 (b) rejection of claim 57 over Meade et al. and the 102 (e) rejection of claim 57 over Blackburn et al. are both maintained.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 57 is rejected under 35 U.S.C. 102(b) as being anticipated by Meade et al. (USPN 6,177,250 01/23/2001).

Meade et al. teach providing an electrode with a covalently attached probe with a sequence substantially complementary to a first domain of a target sequence (see whole document, especially col. 9 lines 63-67 see col. 21 lines 59-60). They also teach a first and second label probe with first or second

Art Unit: 1637

bases at the detection position of the target sequence (interrogation position). They teach a first and second ETM with first and second redox potentials respectively, forming a hybridization complex with the target sequence and determining the nucleotide at the detection position (see col. 7 lines 25-27, col. 21 lines 59-67, col. 22 lines 1-13).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 43-48, 50, 53-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Blackburn et al. (USPN 6,686,150 B1).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Blackburn et al. teach the hybridization complex having a label probe with a first base at a detection position and an ETM with a first redox potential and they teach a label probe with a plurality of first ETMs (see col. 7 lines 20-24, Fig 16C). They teach an electrode with a covalently attached capture probe with a sequence substantially complementary to a first domain of a target sequence and a first label probe with a first base at the detection position of the target sequence and a first ETM with a first redox potential. They also teach a second label probe with a second base at the detection position of the target sequence and a second ETM with a second redox potential, forming a hybridization complex with the

Art Unit: 1637

target sequence and one of the label probes and the capture probe, and determining the nucleotide at the detection position (see col. 7 lines 44-46, Fig 16 H).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meade et al. (USPN 6,177,250 01/23/2001) in view of Heller et al. (USPN 5,605,662, 02/25/1997).

The teachings of Meade et al. are described previously.

Meade et al. do not teach an array (more than two label probes each with an ETM having a redox potential).

Heller et al. teach an array (see col. 6 lines 52-56).

It would have been prima facie obvious to utilize the method of detection of nucleic acids with ETMs as taught by Meade et al. (USPN 6,177,250 01/23/2001) in an array format as taught by Heller et al. (USPN 5,605,662, 02/25/1997). An ordinary practitioner would have been motivated to utilize the method of detection of nucleic acids with ETMs in an array format as taught by Heller et al. (USPN 5,605,662, 02/25/1997) because Heller et al. (USPN 5,605,662, 02/25/1997) recognize the need for controlled multiplex reactions such as nucleic acid hybridizations for detection. An ordinary practitioner would have utilized the ETM labels for detection of nucleic acids in an array format in order to analyze multiple sample nucleic acids in a substantially reduced amount of time as compared to analysis of sample nucleic acids separately.

Art Unit: 1637

Response to Arguments

6. Applicant's arguments filed 18 November 2004, have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., Applicant argues that the currently amended claim includes at least three different ETMs (one electrode and two label probes each comprising an ETM) where each ETM has a different redox potential) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Amended claim 57 does not include three different ETMs, but rather describes the use of two label probes with a first and a second ETM, each ETM having a first and second redox potential respectively. The use of two label probes with a first and a second ETM, each ETM having a first and a second redox potential respectively is anticipated by Meade et al., as Meade meets the elements of this claim. Additionally, the aforementioned claim elements are also anticipated by Blackburn et al., therefore the 102 (e) rejection of claim 57 over Blackburn et al. is hereby maintained.

Claim 57 is amended to recite determining the genotype of an individual by detecting the ETMs. Meade et al. additionally meets this requirement as Meade et al teaches determining the nucleotide at the detection position (see col. 7 lines 25-27, col. 21 lines 59-67, col. 22 lines 1-13). Determining a genotype is interpreted to mean determining a haplotype, and as such reads on determining nucleotides at a detection position. Therefore Meade et al. meets this claim requirement.

Art Unit: 1637

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita, Ph.D. whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday thru Thursday 7:00 A.M. - 5:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571.272.0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

hgc


GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600